

CITRUCEL- methylcellulose powder, for solution
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient CITRUCEL Orange
(in each heaping tablespoon)

Methylcellulose (a non-allergenic fiber) 2g

Active ingredient CITRUCEL Sugar Free
(in each rounded tablespoon)

Methylcellulose (a non-allergenic fiber) 2g

Purpose

Bulk-forming fiber laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 12-72 hours

Warnings

Choking: taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.

Ask a doctor before use if you have

- a sudden change in bowel habits that persists for two weeks
- abdominal pain, nausea or vomiting

Stop use and ask a doctor if

- constipation lasts more than 7 days
- you have rectal bleeding

These could be signs of a serious condition.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **MIX THIS PRODUCT (CHILD OR ADULT DOSE) WITH AT LEAST 8 OUNCES (A FULL GLASS) OF WATER OR OTHER FLUID. TAKING THIS PRODUCT WITHOUT ENOUGH LIQUID MAY CAUSE CHOKING. SEE CHOKING WARNING**
- use product at the first sign of constipation or irregularity
- put one dose in a full glass of cold water
- stir briskly and drink promptly
- drinking another glass of water is helpful

CITRUCEL Orange

Age	Dose
adults & children 12 years of age and over	start with 1 heaping <i>tablespoon</i> . Increase as needed, 1 heaping <i>tablespoon</i> at a time, up to 3 times per day.
children 6 - 11 years of age	start with 2.5 level <i>teaspoons</i> . Increase as needed, 2.5 level <i>teaspoons</i> at a time, up to 3 times per day.
children under 6 years of age	consult a physician

CITRUCEL Sugar Free

Age	Dose
adults & children 12 years of age and over	start with 1 rounded <i>tablespoon</i> . Increase as needed, 1 rounded <i>tablespoon</i> at a time, up to 3 times per day.
children 6 - 11 years of age	start with 2 level <i>teaspoons</i> . Increase as needed, 2 level <i>teaspoons</i> at a time, up to 3 times per day.
children under 6 years of age	consult a physician

Other information (Citrucel Orange)

- **each heaping tablespoon contains:** calcium 80 mg and potassium 105mg
- each heaping tablespoon contributes 60 calories from sucrose and maltodextrin
- store below 77°F (25°C)
- protect contents from humidity
- keep tightly closed

Other information (Citrucel Sugar Free)

- **each rounded tablespoon contains:** calcium 80 mg and potassium 115 mg
- each rounded tablespoon contributes 24 calories from maltodextrin
- store below 77°F (25°C)
- protect contents from humidity
- keep tightly closed
- **Phenylketonurics: CONTAINS PHENYLALANINE** 52mg per adult dose

Inactive ingredients (Citrucel Orange)

citric acid, dibasic calcium phosphate, FD&C yellow #6 lake, maltodextrin, orange flavors (natural and artificial), potassium citrate, riboflavin, sucrose, titanium dioxide, tricalcium phosphate

Inactive ingredients (Citrucel Sugar Free)

aspartame, dibasic calcium phosphate, FD&C yellow #6 lake, malic acid, maltodextrin, orange flavors (natural and artificial), potassium citrate, riboflavin

Questions or comments? (Citrucel Orange)

call toll-free **1-800-897-6081**

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GSK Consumer Healthcare

Warren, NJ 07059

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DIRECTIONS FOR USE (NO SCOOP DOSING):



1. Fill glass with at least 8 oz. of cold water.



2. Measure heaping tablespoon of product (one dose) and stir product into water. Stir briskly and drink promptly.

Questions or comments? (Citrucel Sugar Free)

call toll-free **1-800-897-6081**

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DIRECTIONS FOR USE (NO SCOOP DOSING):



1. Fill glass with at least 8 oz. of cold water.



2. Measure rounded tablespoon of product (one dose) and stir product into water. Stir briskly and drink promptly.

Principal Display Panel

NDC 0135-0089-69

Great Taste

CITRUCEL

METHYLCELLULOSE FIBER THERAPY FOR IRREGULARITY

- Gentle and clinically proven effective*
- Gives you additional fiber to help relieve occasional constipation
- Fiber for irregularity that won't cause excess gas**

orange FLAVOR

NET WT 16 OZ (454 GRAMS)

Great Tasting

CITRUCEL Orange

Citrucel offers these great benefits:

- **Gentle and clinically proven effective** to help relieve occasional constipation*
- **Fiber that won't ferment** to cause excess gas **
- **100% Soluble, gluten-free, non-allergenic fiber**

*When Used As Directed.

**Based On Laboratory Testing. Individual Results May Vary.

TAMPER EVIDENT PACKAGE

DO NOT USE IF FOIL SEAL IS MISSING OR BROKEN.

5E643

NDC 0135-0089-69

Great Taste



CITRUCEL

METHYLCELLULOSE FIBER THERAPY FOR IRREGULARITY

- Gentle and clinically proven effective*
- Gives you additional fiber to help relieve occasional constipation
- Fiber for irregularity that won't cause excess gas**



orange
FLAVOR

NET WT 16 OZ (454 GRAMS)

Principal Display Panel

NDC 0135-0090-74

Great Taste

CITRUCEL

METHYLCELLULOSE FIBER THERAPY FOR IRREGULARITY

- Gentle and clinically proven effective*
- Gives you additional fiber to help relieve occasional constipation
- Fiber for irregularity that won't cause excess gas**

sugar free ORANGE FLAVOR

NET WT 32 OZ (907 GRAMS)

Great Tasting Orange Flavor

CITRUCEL Sugar Free

Citrucel offers these great benefits:

- **Gentle and clinically proven effective** to help relieve occasional constipation*

- **Fiber that won't ferment** to cause excess gas**
 - **100% Soluble, gluten-free, and non-allergenic fiber**
- *When Used As Directed.
 **Based On Laboratory Testing. Individual Results May Vary.

TAMPER EVIDENT PACKAGE

DO NOT USE IF FOIL SEAL IS MISSING OR BROKEN.

5M245



CITRUCEL			
methylcellulose powder, for solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0089

Route of Administration	ORAL
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
METHYLCELLULOSE (4000 MPA.S) (UNII: MRJ667KA5E) (METHYLCELLULOSE (4000 MPA.S) - UNII:MRJ667KA5E)	METHYLCELLULOSE (4000 MPA.S)	2 g in 19 g

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
RIBOFLAVIN (UNII: TLM2976OFR)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics			
Color	ORANGE	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0089-69	454 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	
2	NDC:0135-0089-71	850 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/16/2010	

CITRUCEL
methylcellulose powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0090	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
METHYLCELLULOSE (4000 MPA.S) (UNII: MRJ667KA5E) (METHYLCELLULOSE (4000 MPA.S) - UNII:MRJ667KA5E)		METHYLCELLULOSE (4000 MPA.S)	2 g in 10.2 g	
Inactive Ingredients				
Ingredient Name			Strength	
ASPARTAME (UNII: Z0H242BBR1)				
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MALIC ACID (UNII: 817L1N4CKP)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
POTASSIUM CITRATE (UNII: EE90ONI6FF)				
RIBOFLAVIN (UNII: TLM2976OFR)				
Product Characteristics				
Color	ORANGE	Score		
Shape		Size		
Flavor	ORANGE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0090-70	479 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	
2	NDC:0135-0090-74	907 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	
3	NDC:0135-0090-75	1191 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334		09/16/2010	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

